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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/912,576	07/24/2001	John Thomas Allen	SUREB-57333	6668

39607 7590 10/04/2005

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EXAMINER
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MCKANE, ELIZABETH L

ART UNIT	PAPER NUMBER
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1744

DATE MAILED: 10/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/912,576

Applicant(s)

ALLEN ET AL.

Examiner

Leigh McKane

Art Unit

1744

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 01 June 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,3,4,6,7 and 9-52 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3,4,6,7 and 9-52 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 February 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_

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1. Prosecution on the merits of this application is reopened on claims 1, 3-7, and 9-52 are considered unpatentable for the reasons indicated below.
2. Applicant is advised that the Notice of Allowance mailed is vacated. If the issue fee has already been paid, applicant may request a refund or request that the fee be credited to a deposit account. However, applicant may wait until the application is either found allowable or held abandoned. If allowed, upon receipt of a new Notice of Allowance, applicant may request that the previously submitted issue fee be applied. If abandoned, applicant may request refund or credit to a specified Deposit Account.

***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

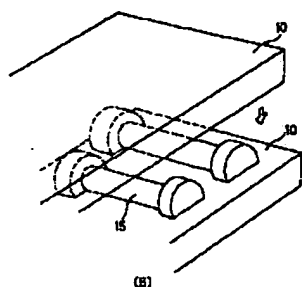
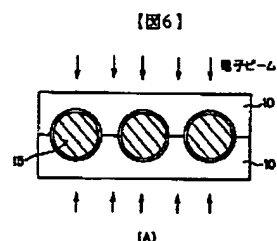
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, 3, 4, 7, 9-11, 13, 14, 17-22, 24-34, 37, 38, 40, 41, 43-52 are rejected under 35 U.S.C. 102(b) as being anticipated by Doi (JP 2000312708, machine translation).

Doi teaches a method and apparatus for electron beam sterilization of articles 15. Doi discloses that the articles 15 absorb radiation at different positions in accordance with irregularities in the characteristics of the articles at the different positions. See paragraphs [0004]-[0008]. The articles are provided in a “container” (lower half of 10 in Figure 6A). To provide a uniformity of dosage, a regulator (upper half) 10 is provided to absorb the radiation passing from a source 20 (Figure 5) wherein the regulator 10 is fabricated of a shape and

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material such that it absorbs radiation passing from the source to the articles at the different positions in the container in accordance with the irregularities in the characteristic of the article



at the different positions to maintain the radiation dose at the different

positions in the article within particular minimum and maximum limits.

The “container” may be moved past the source on a conveyor along with the regulator. See paragraph [0009]. The conveyor moves transverse and substantially perpendicular to the radiation. See Figures 5 and 6A. Doi further teaches that the regulator 10 may be fabricated of a material having a “consistency almost equivalent to an irradiated object” and has a shape/geometry complementary to the object. A suggested material is aluminum. See paragraphs [0021] and [0027]; Figure 6A.

### *Claim Rejections - 35 USC § 103*

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 6, 12, 15, and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Doi.

Doi teaches conveying articles 15 past a radiation source 20 in a direction substantially perpendicular to the direction of radiation and the use of a fixture 10 designed to provide a uniform level of absorbed radiation throughout the article. Therefore, although Doi does not

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specifically disclose that the conveyor moves the articles at a substantially constant speed, it would have been obvious to one of ordinary skill in the art to do so in order to provide a uniform level of absorbed radiation throughout the length of the article. This concept is clearly taught by Doi.

7. Claims 16 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Doi as applied to claims 15 and 32 above, and further in view of Peck et al (U.S. 5,590,602).

With respect to both of claims 16 and 36, Doi is silent with respect to spacing adjacent containers and fixtures by a particular distance when being moved past the radiation source. Peck et al teaches a method and apparatus for electron beam sterilization of articles wherein the articles are conveyed within containers that are spaced from adjacent containers to achieve “optimum article throughput efficiency” (col.5, lines 19-30). Peck et al further discloses that in order to “most efficiently utilize the energy of the radiation beam emitted by the radiation source 10, the spacing between the article carriers 17 as they are transported by the process conveyor 14 past the radiation source 10 must be as small as practically possible.” See col.5, lines 61-65. Therefore, it would have been obvious to space adjacent containers and fixtures being conveyed by the conveyor of Doi by a particular distance within particular limits so as to “most efficiently utilize the energy of the radiation beam emitted by the radiation source”.

As to claim 36 specifically, Doi teaches conveying articles 15 past a radiation source 20 in a direction substantially perpendicular to the direction of radiation and the use of a fixture 10 designed to provide a uniform level of absorbed radiation throughout the article. Therefore, although Doi does not specifically disclose that the conveyor moves the articles at a substantially constant speed, it would have been obvious to one of ordinary skill in the art to do so in order to

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provide a uniform level of absorbed radiation throughout the length of the article. This concept is clearly taught by Doi.

8. Claims 23, 39, and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Doi as applied to claims 21 and 37 above, and further in view of Ichihara (U.S. 6,030,554).

While Doi teaches two regulators 10 (wherein the bottom regulator also functions as a container for the articles) in Figures 6A and 6B, Doi is silent with respect to a separate container for the articles, which container holds the articles and wherein the two regulators are disposed external to the container. However, Ichihara discloses that terminal sterilization, that is the sterilization of an article within its final packaging, is known in the art in the field of electron beam sterilization. See Abstract. In the invention of Ichihara, an article is placed within a container which permits transmission of electron beam radiation, but prevents entry of microorganisms into the container. See col.2, lines 31-39. Therefore, once the article is sterilized, it will not be recontaminated by subsequent packaging. Likewise, one would have found it obvious to package the articles (dialyzers) of Doi prior to sterilization, in order to prevent subsequent recontamination of the dialyzers.


### ***Conclusion***

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leigh McKane whose telephone number is 571-272-1275. The examiner can normally be reached on Monday-Thursday (5:30 am-2:00 pm).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Kim can be reached on 571-272-1142. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
**Leigh McKane**  
**Primary Examiner**  
**Art Unit 1744**

elm  
22 September 2005